REMARKS

Claims 1-3 and 10 are pending and have been rejected. No claims have been canceled.

Drawings

Applicants are submitting along with this response new drawings to correct the objections of the Official Draftsperson.

Information Disclosure Statement

This is being submitted under separate cover.

Election

The Examiner has withdrawn claims directed to non-elected amino acid sequences (i.e., other than SEQ ID NO: 29) on grounds that these other sequences represent distinct patentable inventions and not just different species. Applicants urge that if a generic claim is allowable then the identity of the sequence used is not relevant and requires no search at all. In addition, it is conceded in the Restriction (Paper 5, at page 4, ¶6) that there are no MPEP provisions for inventive groups directed to different products.

In addition, other groups are directed to methods of using the claimed polypeptides so that if such polypeptide is found patentable, its use should be

patentable because the polypeptide would not itself be in the literature so that its use would not be in the prior art either and no additional search is required.

Rejection Under 35 U.S.C. §112, ¶2

Claims 2 and 3 were rejected as indefinite under section 112, paragraph 2. Claim 2 was rejected for use of the phrase "further comprising about the N-terminal two thirds of the sequence selected from SEQ ID NO: 29." Applicants contend that this meaning is clear in that residues 26-186 would be part of the N-terminal two thirds of the recited sequence. Thus, claim 1 recites a polypeptide comprising residues 26-186 and claim 2 is further limited in that it comprises the N-terminal two thirds (i.e., residues 1-186). Claim 2 is therefore more limited than claim 1 and properly depends on claim 1. In the interests of clarity, Applicants have amended this claim to simply recite that the claimed polypeptide comprises the indicated sequence.

Claim 3 was rejected as indefinite for use of the phrase "an amino acid sequence." Applicants do not believe that this is indefinite. This phrase simply refers to the fact that the amino acid sequence of the claimed polypeptide is one of the recited sequences (i.e., it has "an amino acid sequence" that is one of sequences 23-45 and 55). If the claim were limited to SEQ ID NO: 29, the polypeptide would have "the amino acid sequence" of sequence 29. Thus, the claimed polypeptide could be of any size so long as a portion of its amino acid sequence is SEQ ID NO: 29, or one of the other recited sequences. In the interests of clarity, Applicants have amended this claim to simply recite that the claimed polypeptide comprises the indicated sequence.

Rej ction Und r 35 U.S.C. §102

Claims 1-3 and 10 were rejected under section 102(b) as anticipated by Accession No. AC P08191 or Krogfelt et al (1990).

The argument based on Accession No. AC P08191 appears to be that an alignment of the sequence disclosed and that of SEQ ID NO: 29 shows that residues 26-119 are contained within the claimed sequence of residues 26-186.

Applicants respond that this interpretation miss-reads the claim as well as the reference. The claim is directed to an immunogenic polypeptide that comprises a sequence selected from amino acids 26-186 of the recited sequences. This means, for example, that for SEQ ID NO: 29, which is a total of 279 amino acids in length, the claimed immunogenic polypeptide has an amino acid sequence that contains as some portion within it the entirety of residues 26-186 of SEQ ID NO: 29. The Examiner also relies on "the enclosed alignment" but this is an alignment between the protein of Accession No. AC P08191 (a total of 300 amino acids in length and bigger than FimH itself, which is only 279 residues long) and SEQ ID NO: 29, which shows only residues 26-119 of SEQ ID NO: 29 to be common to both proteins. In order to anticipate the claimed polypeptide, the reference must show the sequence of residues 26-186 of one of the recited sequences, such as sequence 29, and not just a segment contained within residues 26-186. Applicants believe that the amendment to claim 1 has made this clearer.

In addition, Krogfelt et al only disclose use of the entire protein or the entire fimbriae. Thus, Figure 2, lane B, of Krogfelt et al (cited in the Office Action) shows a gel with FimH (the entire protein) and that this can bind to mannose (which is itself bound to a carrier – here, bovine serum albumin). The Office Action indicates that Krogfelt

shows FimH bound to a carrier but in fact it is the mannose that is bound to the carrier and not FimH (see Krogfelt et al at page 1995, column 2, second full paragraph, lines 4-6). Conversely, the Applicants have determined that smaller portions of the protein are required for immunogenic activity (here, residues 26-186 of, for example, SEQ ID NO: 29). This discovery is neither anticipated by, nor obvious over, the disclosure of Krogfelt et al.

Krogfelt does not disclose FimH attached to a carrier but only mannose attached to a carrier and does not teach that use of a smaller section of the protein can be used. In addition, Krogfelt utilized the FimH from strain PC31 while Applicant's own disclosure shows that the different strains have different sequences. For example, strain J96 is known in the art, along with its sequence (as noted by Applicants at page 7, line 10), and over the stretch of residues 26-186, it differs from SEQ ID NO: 29 by some 2%. The isolates claimed by Applicant are new and likely to have different sequences from those in the art.

Nor can these references, either separately or in combination, render the claimed immunogenic polypeptide obvious since nothing in these references suggests that less than the entire protein would be useful for forming an immunogenic polypeptide.

In addition, claim 10, directed to a vaccine composition, was also rejected under section 102(b). However, Applicants contend that the fact that such a protein is present in a buffer does not enable its use either as a vaccine or anticipate (or render obvious) the claimed vaccine composition because the prior art proteins do not comprise residues 26-186 of SEQ ID NO: 29 nor disclose any use of those proteins in affording protection against bacterial infection. Conversely, Applicants teach such use (see, for example, the results of Example 1 and table 2, on page 29, of the application, showing

use of strain J96 FimH (SEQ ID NO: 44) anti-sera (from rabbits), said FimH either alone or complexed with FimC chaperone (denoted FimCH in Table 2) in protecting against bladder infection by the different strains of E. coli whose FimH variant proteins are disclosed by Applicants in mice subsequently challenged with such strains of E. coli). Thus, some cross-reactivity is observed between J96 FimH and the strains producing FimH variants disclosed by Applicants. In addition, because the references do not anticipate the claimed polypeptide, they also do not anticipate the composition.

Claim 10, directed to a vaccine, was also rejected based on the same references. Applicant believes that the above-recited arguments apply equally to this claim rejection.

In sum, neither reference relied on in the Office Action discloses an isolated polypeptide, immunogenic or otherwise, comprising residues 26-186 of any of the Applicants' disclosed sequences (SEQ ID NO: 23-45 and 55) and certainly not of SEQ ID NO: 29. Thus, claims 1-3 and 10 should be allowable.

Applicant has included herewith a request for a 1 month extension of time along with the requisite fee. The Commissioner is authorized to charge any and all additional fees to Deposit Account No. 03-0678.

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Respectfully submitted,

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